

## **REMARKS**

### **Request For Entry of Amendment**

While Applicants continue to disagree with the decision of the Board of Patent Appeals and Interferences, in order to advance the prosecution of this application, Applicants are filing a RCE herewith, canceling independent Claims 1, 10 and 51 and dependent Claims 5-7, 18, 19, 62, 63, 66 and 67, and adding new independent Claims 68-73.

It is respectfully requested that this amendment be entered and the amendments and arguments herein considered.

If any fee is needed for these new claims or the entry of this amendment, please charge our deposit account 50/1039.

Applicants will now address each of the Board of Patent Appeals and Interference's/Examiner's rejections and comments in the order in which they appear in the Final Rejection and the decision by the Board.

### **The §102 Rejections**

#### **A.     35 U.S.C. § 102(b) – Serafini**

The Board of Appeals and Interferences decision of September 30, 2004 affirmed the rejection of Claims 1-3 and 5-8 under 35 USC §102(b) for alleged anticipation by Serafini. While Applicants respectfully traverse this rejection based on the reasons of record delineated in Appellants' Brief of May 13, 2002, in order to advance the prosecution of this case, Applicants are canceling independent Claim 1 and adding new independent Claims 68-73. New independent Claims 68-73 are not anticipated nor rendered obvious by Serafini for at least the following reasons.

New independent Claims 68-73 are directed to therapeutic and treatment combinations of a radiosensitizer agent comprising a halogenated xanthene and applied ionizing radiation. In contrast, Serafini fails to teach or suggest any therapeutic or treatment combination of a radiosensitizer agent comprising a halogenated xanthene and applied ionizing radiation. Instead, Serafini is limited to certain diagnostic uses of certain radioactive halogenated xanthenes (i.e., <sup>131</sup>I Rose Bengal).

More specifically, Serafini describes the use of certain highly radioactive forms of Rose Bengal in the medical evaluation of liver function.<sup>1</sup> In a *diagnostic* test, a radioactive form of the compound (radiolabelled with iodine-131 or, as taught by Serafini, with iodine-123) is administered to the patient as an intravenous bolus. The subsequent distribution of the diagnostic agent throughout certain organs of the patient's body is then determined *by detecting the radioactive emissions* resulting from the spontaneous radioactive decay of the radioactive iodine contained in this radiolabelled Rose Bengal. Serafini uses a radiation detection system (i.e., a "scintillation camera") that is placed outside the patient's body, for detecting this spontaneous radioactive decay of the radioactive iodine. (The scintillation camera receives and produces an electrical or other signal based on the detected radiation). Serafini is thus concerned with an application in nuclear medicine where the intrinsic radioactivity of a substance is put to use. The substance in Serafini's case, Iodine-123-labeled-Rose Bengal, *emits* radiation which Serafini reports on for imaging purposes. As seems appropriate, this article appears in a journal directed to nuclear medicine. Fundamentally, this reference indicates the advantage of one radioactive form of Rose Bengal over another, in forming images from the radioactive emissions. There is no disclosure or suggestion of

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<sup>1</sup> Applicants note that the compounds used in radiosensitizer agents, such as the halogenated xanthenes claimed in the present application, are typically non-radioactive.

a radiosensitizer agent, ionizing radiation, or treatment of cancers or tumors, and certainly no disclosure of a combination of a radiosensitizer agent and ionizing radiation.

Hence, Serafini fails to disclose or suggest salient features of the new independent claims of the present application, such as a *therapeutic or treatment combination* consisting of a *radiosensitizer agent and applied ionizing radiation*. Therefore, Serafini cannot anticipate nor render obvious the presently claimed invention.

Further, Serafini fails to teach or suggest any therapeutic or treatment use of a halogenated xanthene. Thus, Serafini fails to disclose use of the halogenated xanthenes in, or as radiosensitizers for, radiosensitization. Accordingly, Serafini completely misses a feature of the present claims, namely therapeutic or treatment use of the halogenated xanthenes when used in combination with applied ionizing radiation.

Accordingly, for at least the above-stated reasons, Serafini does not anticipate nor render obvious the new independent claims, or those claims dependent thereon, which encompass therapeutic or treatment combinations of a radiosensitizer agent and applied ionizing radiation. Thus, Applicants respectfully request favorable consideration of new independent Claims 68-73, and the withdrawal of this rejection.

**B. 35 U.S.C. § 102(b) – Neckers**

The Board of Appeals and Interferences decision of September 30, 2004 also affirmed the rejection of Claims 1-3 and 5-9 under §102(b) for alleged anticipation by Neckers. While Applicants respectfully traverse this rejection based on the reasons of record delineated in Appellants' Brief of May 13, 2002, in order to advance the prosecution of this case, independent Claim 1 has been canceled and new independent Claims 68-73 added, as explained *supra*. New

independent Claims 68-73 are not anticipated nor rendered obvious by Neckers for at least the following reasons.

As explained *supra*, new independent Claims 68-73 are directed to therapeutic or treatment combinations of a radiosensitizer agent comprising a halogenated xanthene and applied ionizing radiation. Neckers fails to teach or suggest any therapeutic or treatment combination of a radiosensitizer agent comprising a halogenated xanthene and applied ionizing radiation. Instead, the disclosure of Neckers is limited to certain physical and chemical properties of certain halogenated xanthenes and their interaction with visible light.

Hence, Neckers fails to disclose or suggest salient features of the new independent claims of the present application, such as a therapeutic or treatment *combination* consisting of a radiosensitizer agent and applied *ionizing radiation*. Therefore, Neckers cannot anticipate nor render obvious the presently claimed invention.

Further, Neckers fails to teach or suggest any radiosensitizer use of a halogenated xanthene. In fact, Neckers does not teach or suggest any interaction of the halogenated xanthenes with any form of ionizing radiation. Thus, Neckers fails to disclose use of the halogenated xanthenes in, or as radiosensitizers for, radiosensitization. Accordingly, Neckers completely misses a feature of the present claims, namely therapeutic or treatment use of the halogenated xanthenes when used in combination with applied ionizing radiation.

For at least the above-stated reasons, Neckers cannot anticipate nor render obvious the presently claimed invention, which encompasses therapeutic or treatment combinations of a radiosensitizer agent and applied ionizing radiation. Thus, Applicants respectfully request favorable consideration of new independent Claims 68-73, and those claims dependent thereon, and request that this rejection be withdrawn.

## **The §103 Rejections**

### **A. 35 U.S.C. § 103(a) – Serafini or Neckers in view of Khaw**

The Board of Appeals and Interferences decision of September 30, 2004 also affirmed the rejection of dependent Claims 4, 15, 18-20 and 55 under 35 USC §103(a) for alleged unpatentability over Serafini or Neckers in view of Khaw. While Applicants respectfully traverse this rejection based on the reasons of record delineated in Appellants' Brief of May 13, 2002, in order to advance the prosecution of this case, Applicants have canceled independent Claims 1, 10 and 51 and added new independent Claims 68-73, as discussed *supra*. New independent Claims 68-73 are patentable over Serafini or Neckers in view of Khaw for the reasons discussed *supra* and at least the following reason.

New independent Claims 68-73 specifically exclude use of immuno-liposomes, which are the key feature in Khaw, as noted on p. 12 of the Board of Appeals decision. Hence, even if the combination of the immuno-liposomes in Khaw with certain unrelated teachings in Serafini or Neckers, were proper, as the Board contends in its decision on pp. 13 and 14 (which Applicants disagree with), the exclusion of such feature from the claimed invention overcomes any basis for the rejection of Claims 68-73 in light of these references.

Accordingly, for at least the above-stated reasons, Khaw in combination with Serafini or Neckers, cannot render obvious the presently claimed invention, which encompasses therapeutic or treatment combinations of a radiosensitizer agent and applied ionizing radiation wherein such radiosensitizer agent excludes the immuno-liposomes that are central to Khaw. Accordingly, Applicants respectfully request favorable consideration of new independent Claims 68-73 and request withdrawal of this rejection.

**B. 35 U.S.C. § 103(a) – Serafini or Neckers in view of Norman**

The Board of Appeals and Interferences decision of September 30, 2004 affirmed the rejection of Claims 10, 51, 52, 56-57 and 60-67 under 35 USC §103(a) as unpatentable over Serafini or Neckers in view of Norman (although the basis for the Board's decision appears to be alleged anticipation by Serafini or Necker under Section 102(b), as discussed on pp. 15-16 of the Board of Appeals decision). While Applicants respectfully traverse this rejection based on the reasons of record delineated in Appellants' Brief of May 13, 2002, in order to advance the prosecution of this case, independent Claims 1, 10 and 51 have been canceled and new independent Claims 68-73 added, as explained *supra*. New independent Claims 68-73 are not anticipated nor rendered obvious by Serafini or Neckers for the reasons discussed *supra*. These claims are also not rendered obvious by any alleged combination of Serafini or Neckers in view of Norman for at least the following reasons.

As explained *supra*, new independent Claims 68-73 are not disclosed or suggested by Serafini or Neckers. For substantially the Applicants' reasons of record, as delineated on pp. 37-41 of Appellants' Brief of May 13, 2002, Norman is not relevant to the claimed invention and new independent Claims 68-73 are patentable over Norman even if combined with Serafini or Neckers.

Unlike the subject of new independent Claims 68-73, Norman concerns use of certain gadolinium-containing compounds that are wholly unrelated to the halogenated xanthenes of the presently claimed therapeutic or treatment combinations. Halogenated xanthenes do not include gadolinium, the chemical element central to the agents in Norman. Moreover, Norman does not suggest or describe any combination of a radiosensitizer agent comprising a halogenated xanthene and ionizing radiation or any potential use of the halogenated xanthenes or a combination of a radiosensitizer agent and ionizing radiation.

Since none of Serafini, Neckers or Norman describes or suggests use of the claimed combination of a radiosensitizer agent comprising a halogenated xanthene and ionizing radiation, these references, whether taken alone or in any hypothetical combination, cannot anticipate nor render obvious the presently claimed invention. Hence, Applicants request favorable consideration of new independent Claims 68-73 and withdrawal of this rejection.

### Conclusion


For at least the above-stated reasons, it is respectfully submitted that the claims of the present application are in an allowable form and are patentable over the cited references. Accordingly, it is requested that the application now be allowed.

If any fee should be due for this Amendment, please charge our deposit account 50/1039.

Favorable reconsideration is earnestly solicited.

Respectfully submitted,

Date: November 24, 2004

  
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